Ambient Water Quality Criteria for the Protection of Human Health

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Science of Environmental Justice

May 26, 2004

Clean Water Act Framework Protecting, Restoring U. S. Waters

Set Standards

Technology-Based Approach

- Effluent limitation guidelines for point sources (available, affordable technology)

Water Quality-Based Approach

- EPA develops water quality criteria guidance
- States develop enforceable water quality standards using criteria

Implement Programs

NPDES Permits

Nonpoint Source Program

Restoring Polluted Waters - TMDLs

Funding & Technical Assistance

Wetlands Protection

Watershed Approaches

Criterion Equation*

$$AWQC = RfD \times RSC \times \left(\frac{BW}{DI + \sum_{i=2}^{4} (FI_i \times BAF_i)} \right)$$

* generalized equation for a noncarcinogen

EPA Revised Human Health Criteria Methodology

- Published 2000
- Incorporated newer methods
  - As described in ’99 Revisions to Cancer Guidelines
  - Newer approaches to non-linear low dose extrapolation
  - Revised consumption estimates
  - Bioaccumulation factors (replaced bioconcentration)
  - Emphasis on use of specific data vs. defaults

Cancer Risk

- New/revised 304(a) criteria for carcinogens will be at a 10^{-6} risk level
- Recommend State/Tribes set criteria at 10^{-5} or 10^{-6}
  - Most highly exposed populations should not exceed 10^{-4} risk level
  - Approval of State-wide 10^{-4} risk level is unlikely

Fish Consumption

- New default rate (for general population/sportfisher) three times higher than old guidance - from 6.5 to 17.5 g/day
  - subsistence fisher = 142.4 g/day
  - women of childbearing age (for developmental effects) = 235.5 g/day*
  - children (90th percentile) = 156.3 g/day

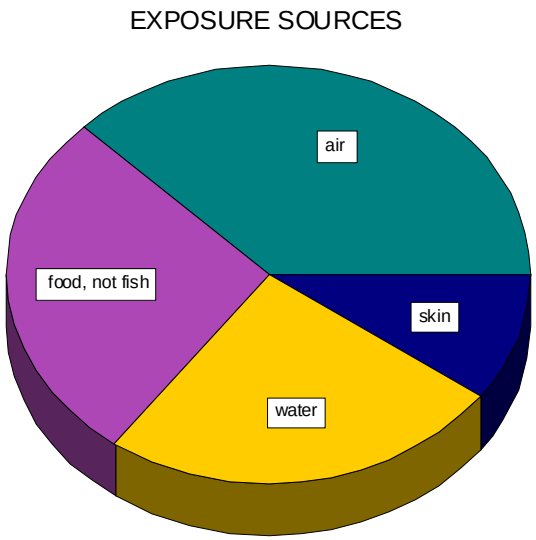
- Preference for States and Tribes to select rates based on local data, more highly exposed populations

Relative Source Contribution (RSC)

- RSC accounts for multiple exposure sources, adjusts RfD downward.
- Final Methodology is first publication of the revised OW RSC policy.
- The RSC policy should be harmonized with drinking water MCLGs.

What Is Relative Source Contribution?

A way to account for all sources of exposure in setting a criterion or standard

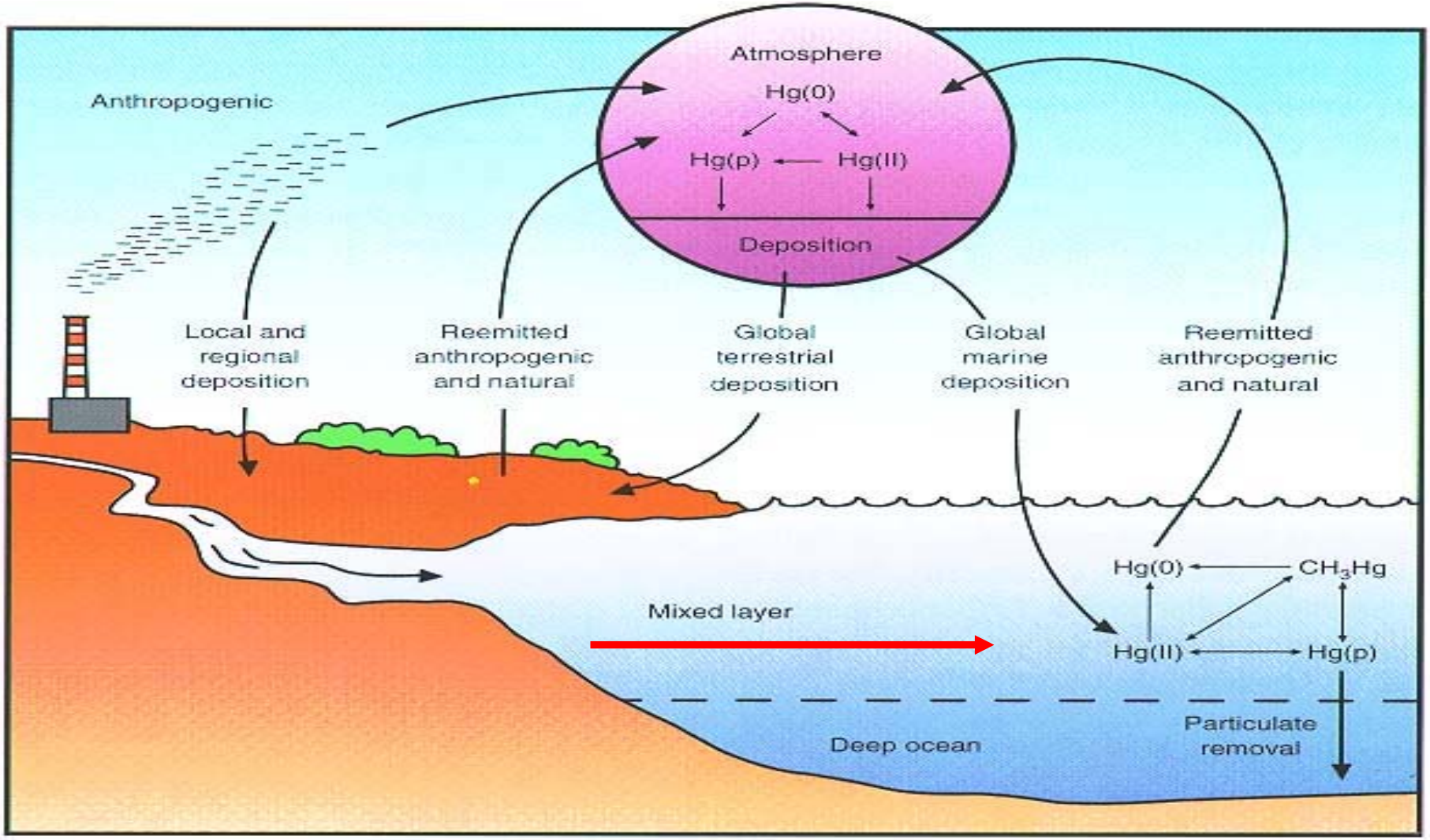


Methodology has flow chart on weighing and using data

Bioaccumulation Factors

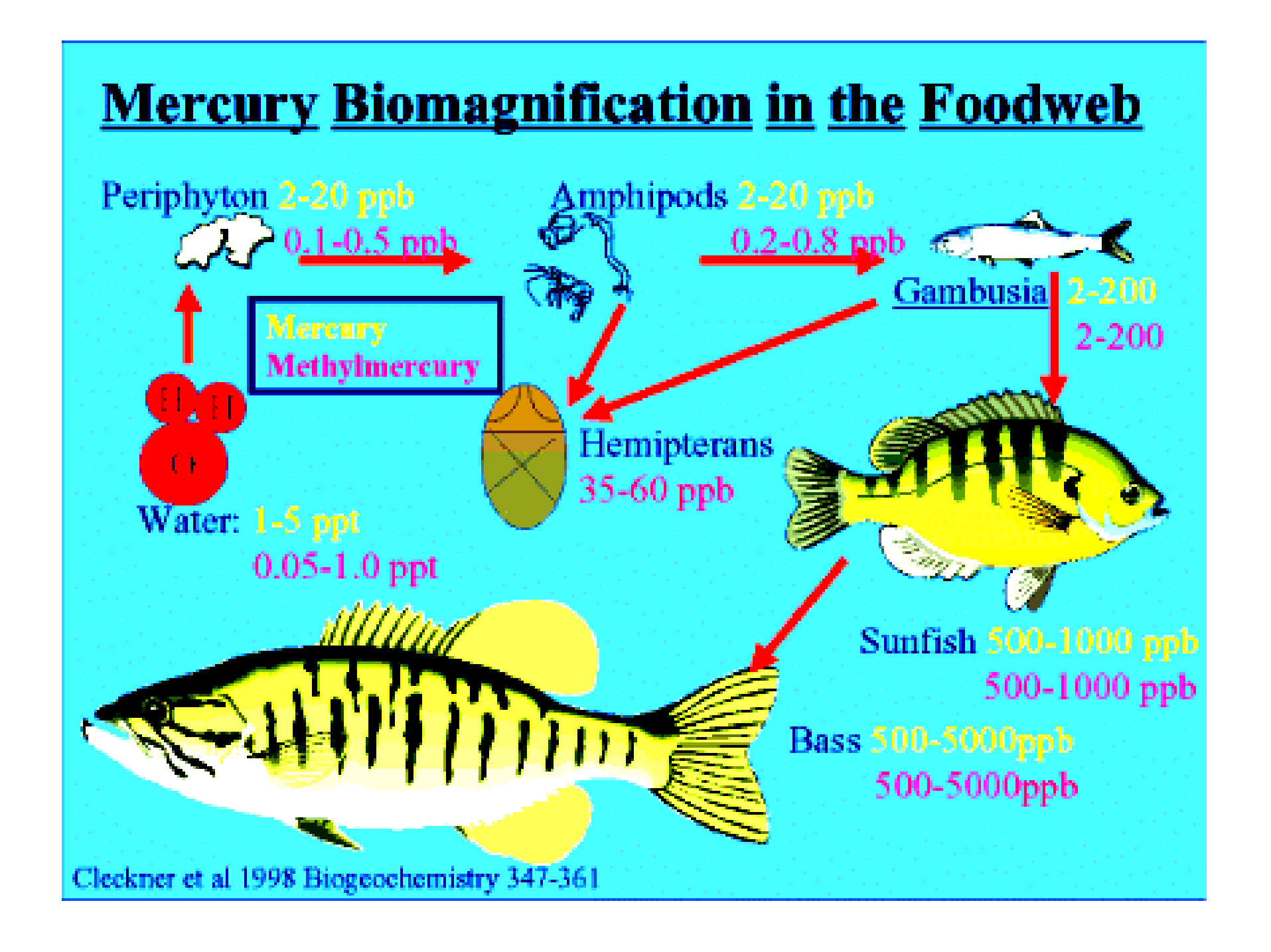
- BAFs incorporate uptake through food chain, thus are better exposure predictors than BCFs
- A hierarchy of BAF methods provides flexibility to EPA and states/tribes
- Science generally supported but somewhat controversial

Geochemical Cycle of Mercury



Adapted from US Dept. of Interior's Report on Hg in the Florida Everglades

Mercury Biomagnification in the Foodweb



Cleckner et al 1998 Biogeochemistry 347-361

Implementation by States/Tribes

- Greater role for States/Tribes, more flexibility
  - Risk assessment decisions
  - Adapting criteria to local conditions
  - Encouraging peer review of criteria
- Coordinating with implementation staff to address likely concerns

2001 MeHg Criterion at a glance

- Old criteria= 50 ng/L water, new= 0.3 mg/Kg wet weight fish tissue
- First CWA 304(a) criterion to be expressed as fish tissue rather than water column value
- RSC lowered RfD by ~30% to allow for consumption of marine fish
- Exposure based on general population fish consumption rate 17.5 g/day
- Peer review did not support use of National BAFs for MeHg due to current data/science limitations

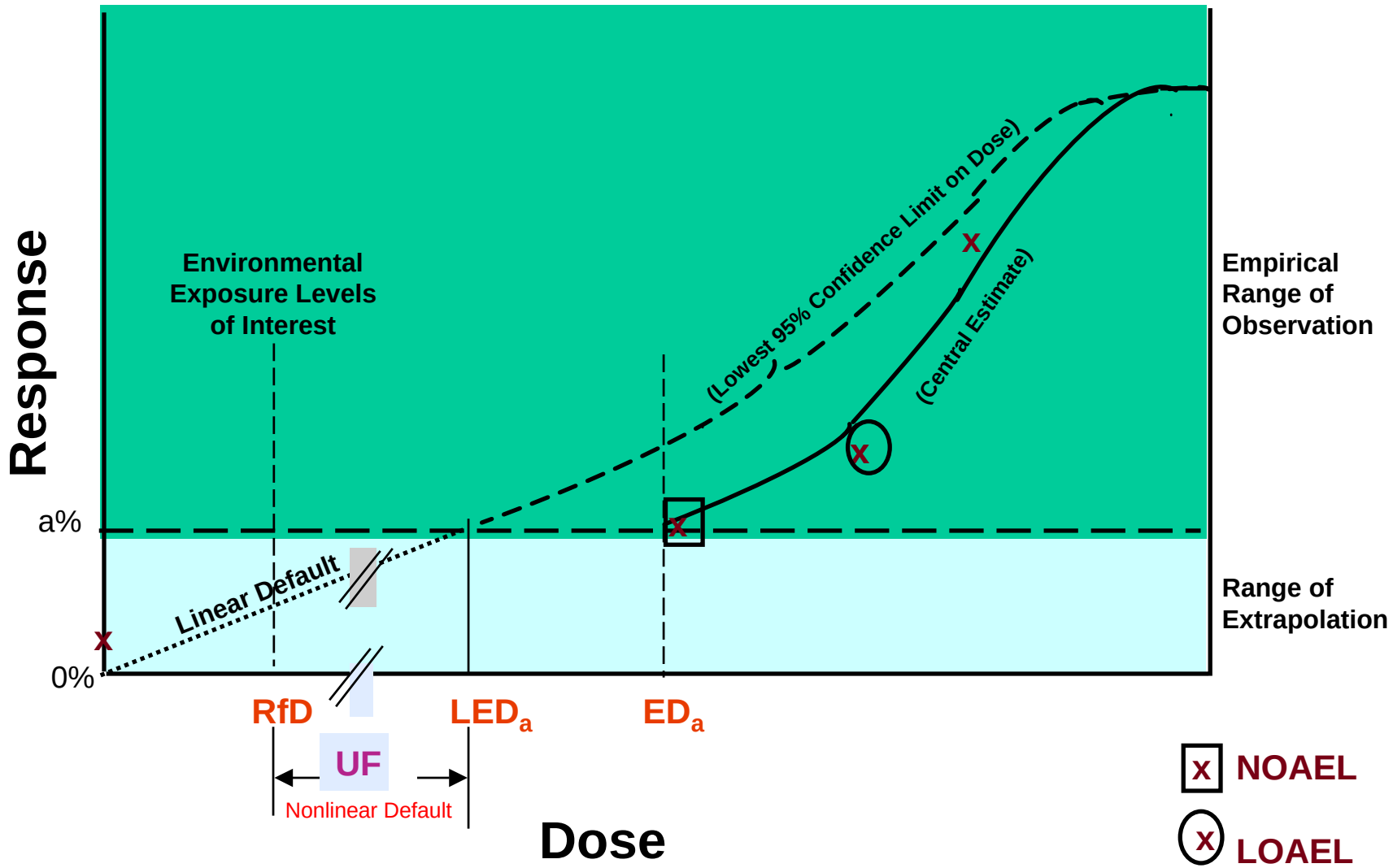
RfD 2001

- RfD = 0.1μg/kg/day
- Based on NRC and external scientific input
- BMDL of 1.0 μg/kg/day -- from neuropsychological effects in Faroese children exposed *in utero* through maternal seafood consumption
- No data to support separate RfD for children
- Applicable to lifetime daily exposure for all populations including sensitive subgroups; not restricted to pregnancy or developmental periods

Bioaccumulation Factor (BAF) Issues

- EPA developed draft national BAF for freshwater
  - Insufficient data for estuarine BAF
- Vary 2 orders of magnitude
  - 50, 000 to 10,000,000
- Peer review did not support National BAFs for Hg due to current data/science limitations
- We did not use a BAF for the criterion
- We suggest use site-specific BAF, model, or draft default BAFs as last choice

Dose Response -- general



Pharmacokinetics UF

- Variability around 2- 3 fold
- Dose conversion -- Assumed cord Hg level = maternal Hg level Publications show that maternal and cord blood Hg are not the same
  - When we did RfD data were judged insufficient for numerical adjustment
  - Stern and Smith (2003) -- cord/ maternal ratio is 1.7 (upper 95th is 3.4)

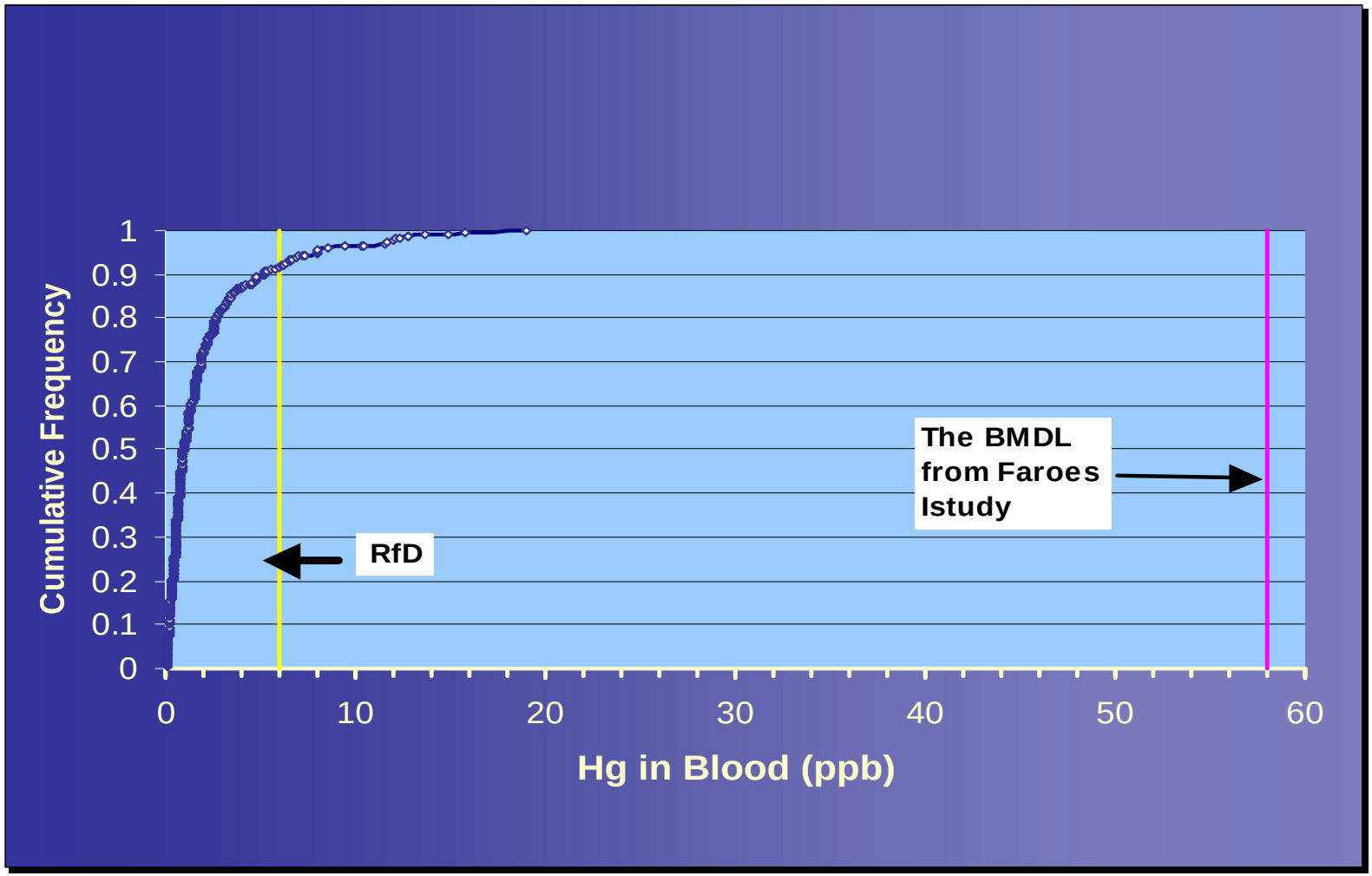
Uses of Criterion

- State Standards
- TMDLs
- Discussions of waste reduction, pollution prevention
- Fish Advisories

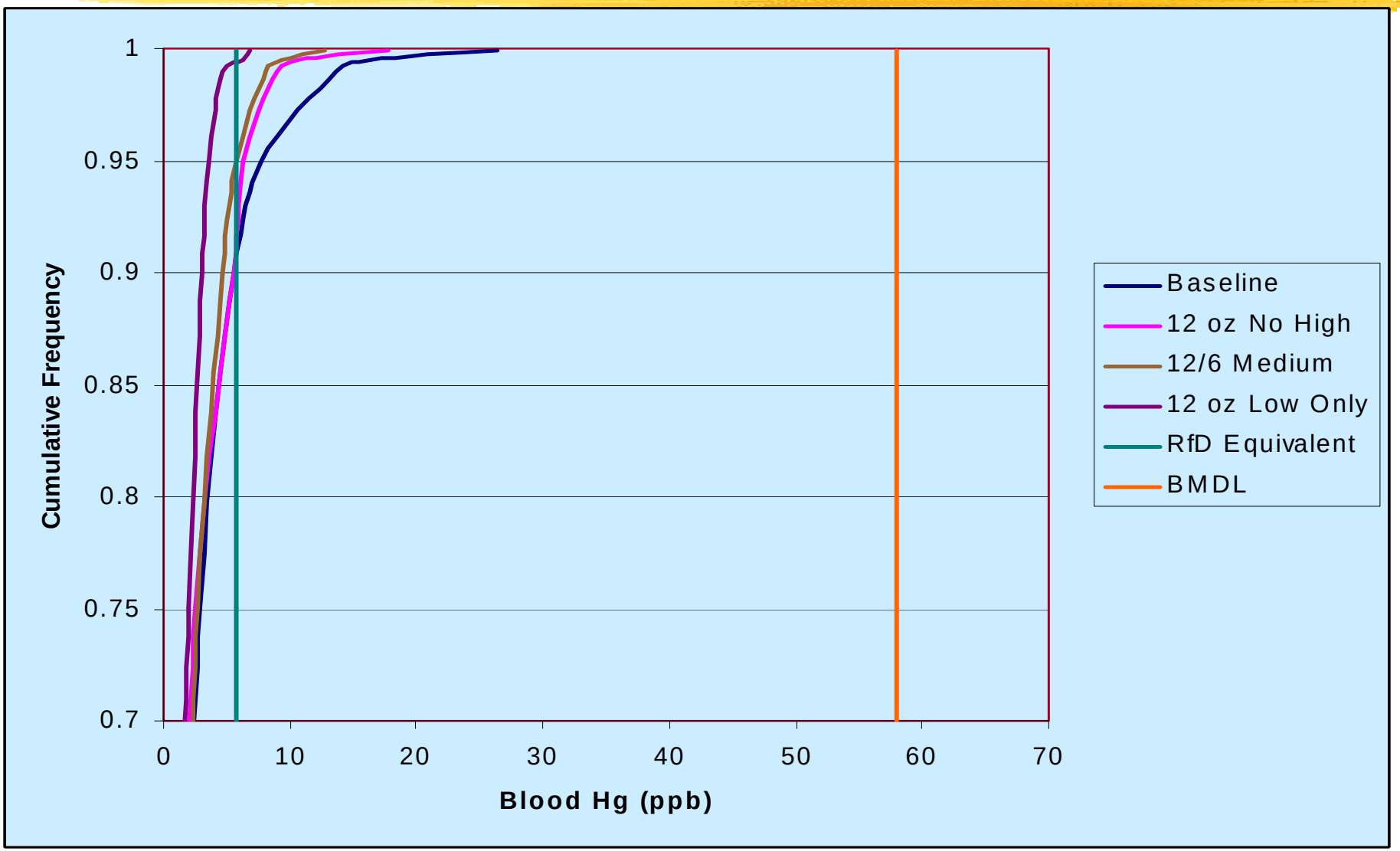
Why Do an Advisory?

- There is lag time between any Hg remediation and decrease in exposure (through consumption of fish)
- Purposes of advisory
  - Decrease % of population at an “unacceptable” mercury level
  - Decrease mercury exposure in entire population potentially at risk

NHANES – Blood Mercury Levels in Women of Childbearing Age



Exposure Predictions



Summary

- EPA's RfD was used as comparison point for measured and modeled blood mercury levels.
- Exposure assessment was reviewed and revised; baseline very closely approximates the NHANES data for blood hg in women of child-bearing age.
- Analysis of scenarios predicts greatest reduction in Hg blood level and percent of women in excess of RfD when both amount and type of fish is restricted.
- This is reflected in the jointly issued advice on fish consumption.

Advice for women of childbearing age and young children

1. *Do not eat Shark, Swordfish, King Mackerel, or Tilefish because they contain high levels of mercury*
2. *Eat up to 12 ounces (2 average meals) a week of a variety of fish and shellfish that are lower in mercury.*

- *Five of the most commonly eaten fish, low in mercury:*

  shrimp, canned light tuna, salmon, pollock, catfish
- *Another commonly eaten fish, albacore ("white") tuna has more mercury than canned light tuna. So, when choosing your two meals …, you may eat up to 6 ounces (one average meal) of albacore tuna per week*

3. *Check local advisories about the safety of fish caught by family and friends in your local rivers and coastal areas. If no advice is available, eat up to 6 ounces (one average meal) per week of fish you catch from local waters, but don't consume any other fish during that week.*

FYI Lots of Information on the RfD and Fish Advice

RfD History

- 1986 used data from Iraqi adults
  - Paresthesia was endpoint
  - 0.3µg/kg bw /day
  - Concern that not protective of developmental effects
- 1997-- data from Iraqi *in utero* exposure
  - 81 mother- child pairs (Marsh et al 1987)
  - All effects – including developmental delays (late walking and talking)
  - 0.1µg/kg bw /day

What we know about MeHg in Humans – newer data

- Newer studies focused on Children
  - New Zealand
  - Seychelles
  - Faroes – 2 cohorts
  - Madeira
  - Peru
  - Canada
- Studies in adults
  - Amazon
  - Finland
  - Japan
  - Canada
  - U.S.
  - Europe and Israel

Comparison of BMDLs and RfDs

Test	BMDL ppb cord mercury	RfD ŝg/kg/day	Test	BMDL ppb cord mercury	RfD ŝg/kg/day
BNT Faroes			**Geometric mean**		
Whole cohort	58	0.1	Whole cohort	68	0.1
PCB adjusted	71	0.1	PCB adjusted	65	0.1
Lowest PCB	40	0.1	Lowest PCB	34	0.1
CPT Faroes			**Median values**		
Whole cohort	46	0.1	Faroes	48	0.1
PCB adjusted	49	0.1	New Zealand	24	0.05
Lowest PCB	28	0.05			
CVLT Faroes	103	0.2	**Smoothed values**		
Whole cohort	78	0.1	BNT Faroes	48	0.1
PCB adjusted	52	0.1	CPT Faroes	48	0.1
Lowest PCB			CVLT Faroes	60	0.1
			Finger Tap Faroes	52	0.1
			MCCPP New	28	0.05
Finger Tap Faroes			Zealand	32	0.1
Whole cohort	79	0.1	MCMT New Zealand	32	0.1
PCB adjusted	66	0.1			
Lowest PCB	24	0.05	**Integrative**		
			All endpoints		

Endpoint – Bottom Line

- Few deviations from RfD = 0.1 µg/kg bw/day; four are at 0.05; one at 2.0.
  - RfD is based on several scores from the Faroes measures. "The test scores are all indications of neuropsychological processes involved with a child's ability to learn and process information."
  - In Criteria Document, used BNT as example – BMDL = 58 ug mercury / L maternal blood

What do these tests mean?

- “indications of neuropyschological processes involved with a child’s ability to learn and process information”
- e.g. BNT assesses expressive vocabulary, related to reading and school performance

  CPT reaction time -- vigilance, attention, information processing speed – intelligence, school behavior and performance

Uncertainty Factor

- Use an uncertainty factor of 10
  - PK variability and uncertainties = 3
  - Pharmacodynamic variability & uncertainty = 3
  - Additional concerns:
    - Lack of 2-generation repro assay
    - Inability to quantify long term sequelae
    - Selection of critical effect (concern for observable effects below the BMDL)

What about Seychelles?

- Myers, Davidson, Cox et al, 2003
  - “good” study”, 717 9-year old children
  - Tests of cognition (BNT, CVLT, WISC III full scale, W-J) for motor, perceptual motor and memory, attention and behavior (CPT)
  - Prenatal MeHg associated only with decreased score, one improved score; some indication of postnatal MeHg effect (still being analyzed)

What's Likely to Change the Reference Dose?

- Most likely change will reflect the concentrations of CH_3Hg in fetal blood compared with maternal blood CH_3Hg concentrations.
- *Additional information on additional groups at risk – for example, increased risk of heart disease associated with increased exposure to methylmercury*.
- Additional adverse health effects having an effect at lower concentrations than the current RfD.

What are these effects likely to be?

- Cardiovascular
  - Effects in children – Sorensen et al ’99, blood pressure – below BMD
  - Effects in adults – Guallar et al ‘02; Salonen et al ’95, myocardial infarction
- Immunological
- Endocrine Disruption

Effects only now being identified.

Doses producing effects not yet clarified.

Dose-response not yet determined.

Modeling – the short story

- Use K-power model (K ❍1)
- For BMD based on Faroes data choose P_0 = 0.05, BMR = 0.05
  - BMD is dose that results in increased probability if abnormal by a benchmark response; from P_0 for unexposed to P_0 + BMR for exposed.
  - Choices above = judgment that performance in lowest 5% is abnormal and that BMD = doubling of portion of pop. with adverse effect – 10% vs. 5%

Ingested Dose

- C = BMDL = 58 ppb in cord blood
- b = elimination constant = 0.014
- V = blood volume = 5L
- A = absorption factor = 0.95
- f = fraction abs dose in blood = 0.059
- bw = body weight = 67 kg

$$d = \frac{C \times b \times V}{A \times f \times bw} = \frac{58 \mu g/L \times 0.014\ days^{-1} \times 5L}{0.95 \times 0.059 \times\ 67kg} = 1.081 \mu g/kg - day$$

Ingested Dose -- 2

- Dose conversion -- Assume cord Hg level = maternal Hg level (uncertainty)
  - Publications show that maternal and cord blood Hg are not the same
  - When we did RfD data were judged insufficient for numerical adjustment
  - Stern and Smith (2003) -- cord/ maternal ratio is 1.7 (upper 95th is 3.4)

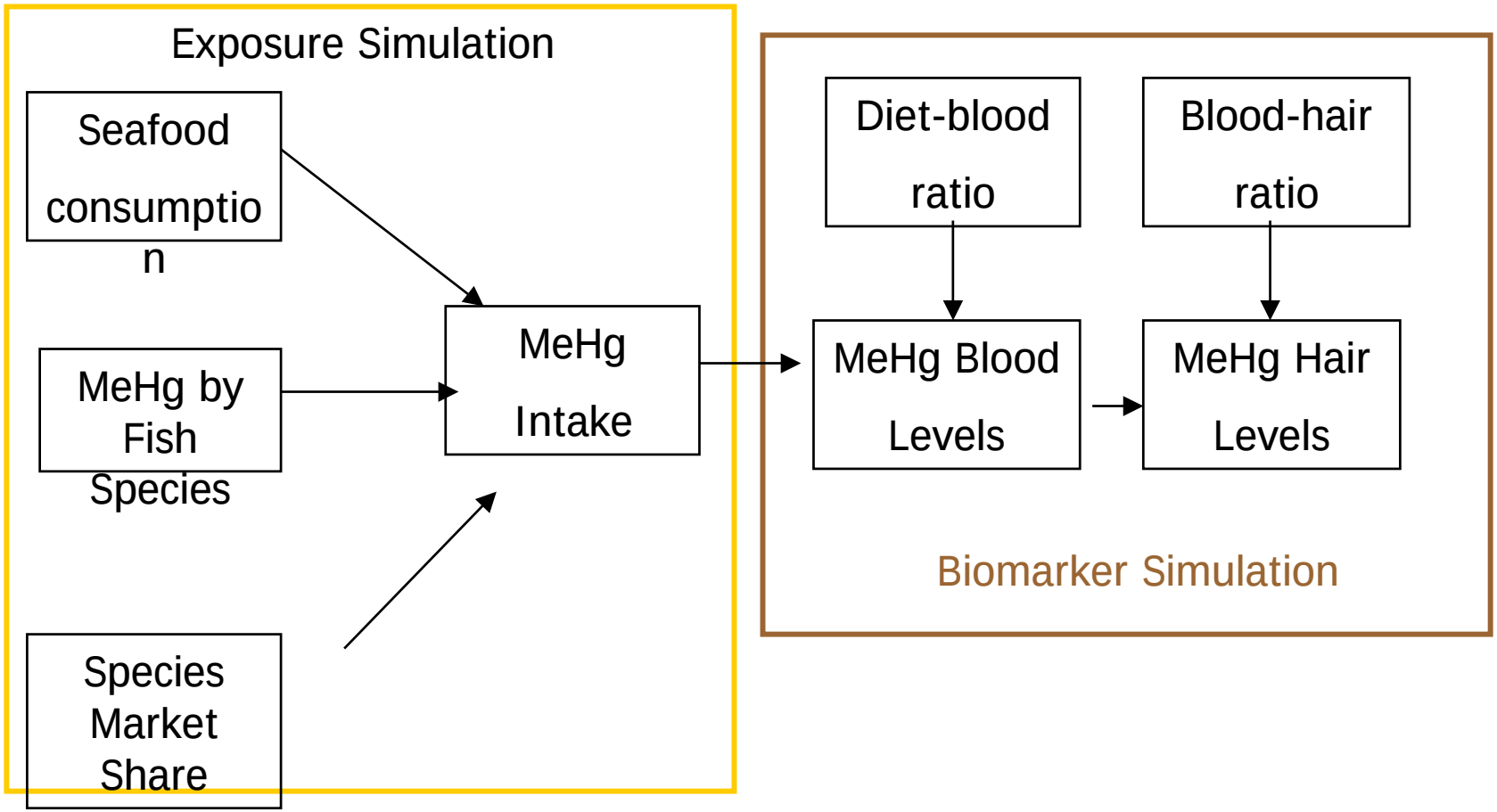
Limits on Methylmercury Considered Fetal Protective

- US EPA - 0.1 ug/kg/day, 1.1 ppm Hg hair, 5.8 µg / litre blood
- ATSDR - 0.3 ug/kg/day
- Health Canada - 0.2 ug/kg/day
- EU - 0.1 ug/kg/day
- WHO - 0.2 ug/kg/day

Why Was the Exposure Assessment Done?

- Response to 2002 – FDA Food Advisory recommendation on the 2001 fish advice
  - Publish a quantitative exposure assessment used to develop the advisory
  - Develop specific recommendations for canned tuna, based on a detailed analysis of what contribution canned tuna makes to overall methyl mercury levels in women

MeHg Exposure Model Overview



FDA 2003 Mercury Testing, 12 Species

- Samples were fresh, refrigerated or frozen
- Each sample tested was composite of 12 individual samples
- Tested in FDA laboratories
- Used standard methods for total mercury

Mercury in Fish and Shellfish

	OLD DATA			NEW DATA (2003)		
	MEAN	**RANGE**	**n**	**MEAN**	**RANGE**	**n**
Bluefish	0.30	0.20-0.40	2	0.318	0.139-0.479	21
Croaker*	0.28	0.18-0.41	15	0.054	0.013-0.096	21
Grouper*	0.27	0.19-0.33	48	0.569	0.072-1.205	20
Crawfish/crayfish	NA	NA	NA	0.028	0.014-0.047	20
Trout Freshwater	0.42	1.22 (max)	NA	NA	NA	NA
Farm Raised Trout	NA	NA	NA	0.033	0.015-0.110	15
Orange Roughy	0.58	0.42-0.76	9	0.485	0.013-0.762	20
Red Snapper	0.60	0.07-1.46	10	0.154	0.077-0.395	12
Trout Seawater	0.27	ND-1.19	4	0.328	0.022-0.744	20
Tilefish*	1.45	0.65-3.73	60	NA	NA	NA
Golden Tilefish	NA	NA	NA	0.208	0.055-1.123	20
Whitefish*	0.16	ND-0.31	2	0.068	0.027-0.137	14
Black Sea Bass	NA	NA	NA	0.127	0.058-0.352	20
Sardine	NA	NA	NA	0.016	0.004 - 0.035	21

2003 Testing of Canned Tuna

- 75% major brands
- 25% store, local or other brands
- Representative of the volume and type of major and local brands and packing medium (spring water, broth, oil) in area
- Samples collected in Los Angeles, San Francisco, Seattle, Chicago, Dallas, New England, New York, Florida.

Mercury in Canned Tuna

	OLD DATA			NEW DATA (2003)		
	MEAN	**RANGE**	**n**	**MEAN**	**RANGE**	**n**
Canned tuna	0.17	0.000-0.75	248	NA	NA	NA
Albacore/ white tuna	0.29	ND- 0.49	17	0.358	0.03-.85	170
Light tuna	0.12	ND-0.75	225	0.123	0.00-0.53	119

Advisory Scenarios

- Limit Total Seafood Consumption
  - 6, 12, or 18 oz per week without regard to species.
- Restrict Species Consumed
  - No limit on amount of fish consumed.
  - Consumption limited to either middle or low groups (No High), or low group (Low Only).
    - Where seafood from the restricted group(s) is specified, the serving is replaced by a random selection from a market-share distribution of low mercury species.
- Restrict Both Amount and Species

Estimation of Blood or Hair Hg Predicated on Scenarios

- Scenarios – weekly levels of fish consumption
  - e.g. No dietary exclusions at all or
  - 12 oz /wk of low mercury fish
- For the scenarios fish were divided into high, medium and low MeHg
  - High: Swordfish, Shark, Tilefish, King Mackerel
  - Medium: e.g. Albacore Tuna, Halibut, Tuna steaks, Rockfish, Haddock, American Lobsters
  - Low: e.g. Light Tuna, Cod, Pollock, Catfish, Shrimp, Salmon, Flatfish, Scallops, Clams, Sardines, Oysters

Review and Revision

- Quantitative exposure assessment developed in early 2003.
- Presented publicly as a poster in March 2003
- External peer review in August 2003
  - Written response by EPA / FDA available on Web. (www.cfsan.fda.gov, www.epa.gov/ost/fish)
  - Revised exposure assessment December 2003
  - New data on mercury levels in fish
  - Comments from the peer review

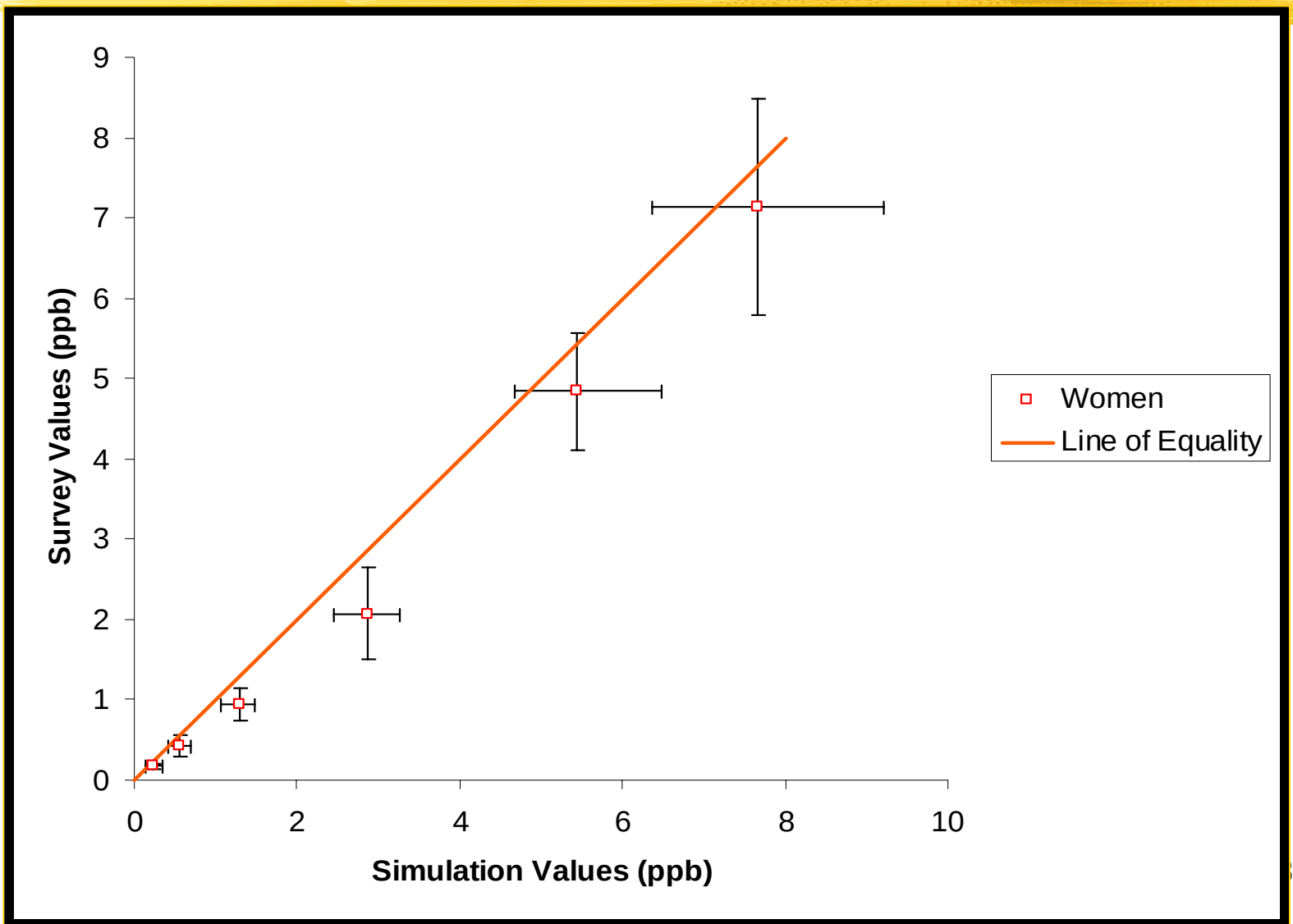
Has Been Revised and Expanded

Some changes in response to review

- More categories of fish added; new data on [Hg]
- Correction for water lost from food preparation
- Parameters in consumption frequency chosen to reflect NHANES
- Slight increase in number of consumers
- Variation in consumer fish choice (changed to individual variable from population variable)
- Scenarios changed to reflect limit on amount of fish consumed, type of fish consumed and limits on both
- Body weight scaling changed

Blood MeHg: Simulation vs. NHANES

Women of Childbearing Age



Hg Concentration Groups

High	Medium		Low	
Swordfish	Grouper	Sablefish	Blue crabs	Catfish
Shark	Orange Roughy	Halibut	Snow crab	Whitefish
King Mackerel	Tuna, Albacore	Rockfish	Cod	Croaker
	Trout, Saltwater	Haddock	Tuna, Light	Scallops
	Tuna, Steaks	Snapper	Sea Bass	Flatfish
	Spiny Lobster	Bluefish	Trout, freshw.	Crawfish
	Dungeness Crab	Lobster	Perch, freshw.	Salmon
			King Crab	Shrimp
			Blue Crab	Clams
			Ocean Perch	Tilapia
			Oysters	Sardines

Advisory Scenario Simulations: Total Consumption Limits

	Baseline	18 oz/week	12 oz/week	6 oz/week
Average	**2.3 (2.1, 2.6)**	**2.2 (2.0, 2.5)**	**2.1 (1.9, 2.3)**	**1.7 (1.5, 1.8)**
Median	**1.3 (1.1, 1.5)**	**1.3 (1.1, 1.5)**	**1.3 (1.1, 1.5)**	**1.2 (1.0, 1.4)**
90th Percentile	**5.5 (4.7, 6.5)**	**5.4 (4.6, 6.4)**	**5.1 (4.4, 5.7)**	**3.5 (3.3, 3.8)**
95th Percentile	**7.7 (6.4, 9.2)**	**7.4 (6.2, 8.9)**	**6.5 (5.7, 7.2)**	**4.2 (3.9, 4.5)**
99th Percentile	**13.6 (10.8, 20.2)**	**11.7 (10.2, 14.4)**	**9.5 (8.4, 11.3)**	**6.2 (5.3, 8.2)**
99.5th Percentile	**16.4 (13.1, 25.9)**	**13.7 (11.4, 17.1)**	**11.5 (9.4, 14.8)**	**7.9 (6.4, 10.6)**
99.9th Percentile	**26.3 (17.5, 52.0)**	**20.7 (14.1, 35.4)**	**18.8 (12.8, 24.9)**	**12.2 (8.5, 15.1)**
% > RfD	**8.8** (6.4, 12.0)	**8.5** (6.3, 11.4)	**7.1** (4.8, 9.4)	**1.3** (0.8, 2.2)

All units are ppb, with confidence limits in parentheses

Advisory Scenario Simulations: Species Consumption Limits

	Baseline	No High	Low Only
Average	**2.3** (2.1, 2.6)	**2.3** (2.0, 2.5)	**1.7 (**1.5, 1.9)
Median	**1.3** (1.1, 1.5)	**1.3** (1.1, 1.5)	**1.0** (0.8, 1.2)
90th Percentile	**5.5** (4.7, 6.5)	**5.3** (4.6, 6.2)	**3.8** (3.3, 4.4)
95th Percentile	**7.7** (6.4, 9.2)	**7.4** (6.3, 9.4)	**5.4** (4.4, 6.7)
99th Percentile	**13.6** (10.8, 20.2)	**13.1** (10.5, 20.3)	**8.8** (7.0, 14.3)
99.5th Percentile	**16.4** (13.1, 25.9)	**16.1** (11.8, 27.1)	**10.4** (8.0, 16.7)
99.9th Percentile	**26.3** (17.5, 52.0)	**26.6** (17.9, 49.6)	**14.4** (10.1, 24.7)
% > RfD	**8.8** (6.4, 12.0)	**8.5** (6.3, 11.4)	**4.2** (2.3, 6.5)

All units are ppb, with confidence limits in parentheses

Advisory Scenarios: Limit Combinations

Scenario	High	Middle	Low	Total
12 oz No High	None	12 oz/wk	12 oz/wk	12 oz/wk
12 oz Variety	None	6 oz/wk	12 oz/wk	12 oz/wk
12/6 Albacore	None	6 oz/wk	12 oz/wk	12 – Albacore oz/wk
12/6 Medium	None	6 oz/wk	12 oz/wk	12 – Medium oz/wk
12 oz Low Only	None	None	12 oz/wk	12 oz/wk

Advisory Scenario Simulations: Limit Combinations

	Baseline	12 oz No High	12 oz Variety	12/ 6 Albacore	12/ 6 Medium	12 oz Low Only
Average	**2.3** (2.1, 2.6)	**2.0** (1.8, 2.2)	**2.0** (1.8, 2.2)	**2.0** (1.8, 2.2)	**1.9** (1.7, 2.1)	**1.5** (1.3, 1.7)
Median	**1.3** (1.1, 1.5)	**1.3** (1.1, 1.5)	**1.3** (1.0, 1.5)	**1.2** (1.1, 1.5)	**1.3** (1.1, 1.5)	**0.5** (0.4, 0.6)
90th Percentile	**5.5** (4.7, 6.5)	**4.9** (4.4, 5.5)	**4.9** (4.3, 5.6)	**4.8** (4.3, 5.4)	**4.7** (4.2, 5.2)	**2.0** (1.8, 2.3)
95th Percentile	**7.7** (6.4, 9.2)	**6.3** (5.7, 7.0)	**6.2** (5.5, 6.9)	**6.0** (5.5, 6.7)	**5.7** (5.1, 6.5)	**3.6** (3.1, 4.0)
99th Percentile	**13.6** (10.8, 20.2)	**9.0** (8.0, 11.2)	**9.1** (8.0, 10.7)	**8.8** (7.4, 11.3)	**8.0** (6.9, 9.4)	**4.6** (4.0, 5.3)
99.5th Percentile	**16.4** (13.1, 25.9)	**10.6** (9.1, 13.7)	**10.7** (9.1, 12.8)	**10.6** (8.4, 14.1)	**9.3** (7.7, 11.3)	**6.3** (5.4, 8.2)
99.9th Percentile	**26.3** (17.5, 52.0)	**17.8** (12.4, 25.7)	**15.3** (12.0, 18.1)	**17.8** (12.0, 23.9)	**12.7** (9.7, 15.2)	**6.9** (5.8, 8.8)
% > RfD	**8.8** (6.4, 12.0)	**6.7** (4.8, 8.8)	**6.2** (4.2, 9.0)	**5.9** (3.9, 8.2)	**4.8** (3.0, 7.4)	**1.9** (0.5, 3.7)

all units are ppb, with confidence limits in parentheses